

BECKMAN

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K964010

Summary of Safety & Effectiveness
IMAGE™ Immunochemistry System Apolipoprotein A-1 (APA) and B (APB) Reagents

1.0 Submitted By:

Margie George
Project Manager, Systems Development
Beckman Instruments, Inc.
200 S. Kraemer Blvd., W-337
Brea, California 92822-8000
Telephone: (714) 961-3765
FAX: (714) 961-3759

2.0 Date Submitted:

03 Oct 1996

3.0 Device Name(s):

3.1 Proprietary Names

IMAGE™ Immunochemistry System Apolipoprotein A-1 Reagent
IMAGE™ Immunochemistry System Apolipoprotein B Reagent

3.2 Classification Names

Lipoprotein test system (21 CFR 862.1475)

4.0 Predicate Device(s):

Beckman Immunochemistry Systems Apolipoprotein A-1 Reagent, K862019
Beckman Immunochemistry Systems Apolipoprotein B Reagent, K 862386

5.0 Description:

The IMAGE System Apolipoprotein A-1 (APA) and B (APB) Reagents are designed for optimal performance on the IMAGE Immunochemistry System. They are intended for use in the quantitative determination of apolipoprotein A-1 and B concentrations in human serum samples.

6.0 Intended Use:

The IMAGE Immunochemistry System Apolipoprotein A-1 (APA) and B (APB) Reagents, in conjunction with Beckman Apolipoprotein Calibrator (APO Cal), are intended for use in the quantitative determination of apolipoprotein A-1 and B in human serum samples by nephelometric immunoassay. These assays are designed for use with the IMAGE Immunochemistry System.

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7.0 Comparison to Predicate(s):

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

Reagent	Aspect/Characteristic	Comments
SIMILARITIES		
IMMAGE System APA Reagent	Assay method - rate nephelometry	Same as Beckman Immunochemistry Systems Apolipoprotein A-1 Reagent
	Sample/reagent ratios	
	Measuring Range: Initial 25 - 255 mg/dL Extended 25 - 450 mg/dL	
	Antibody	
DIFFERENCES		
IMMAGE System APA Reagent	Reaction Temperature	IMMAGE System APA assay runs at 37°C and the predicate runs at 26.7°C.
	Reagent Container	IMMAGE reagent is stored in a plastic cartridge and the predicate reagent is stored in glass vials.

Reagent	Aspect/Characteristic	Comments
SIMILARITIES		
IMMAGE System APB Reagent	Assay method - rate nephelometry	Same as Beckman Immunochemistry Systems Apolipoprotein B Reagent
	Sample/reagent ratios	
	Measuring Range: Initial 35 - 255 mg/dL Extended 35 - 450 mg/dL	
	Antibody	
DIFFERENCES		
IMMAGE System APB Reagent	Reaction Temperature	IMMAGE System APB assay runs at 37°C and the predicate runs at 26.7°C.
	Reagent Container	IMMAGE reagent is stored in a plastic cartridge and the predicate reagent is stored in glass vials.

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, and imprecision experiments that relate results obtained from the Beckman Immunochemistry Systems Apolipoprotein A-1 and B Reagents to the IMMAGE APA & APB Reagents.

Method Comparison Study Results IMMAGE APA & APB Reagents vs. Beckman Apolipoprotein A-1 and B Reagents

Analyte	Slope	Intercept	r	Predicate
IMMAGE APA	0.998	1.86	0.983	Beckman Apolipoprotein A-1 Reagent on the ARRAY
IMMAGE APB	1.030	-1.34	0.991	Beckman Apolipoprotein B Reagent on the ARRAY

Stability Study Results

Reagent	Product Claim
IMMAGE APA	24 months shelf-life 14-day on board 14 day calibration stability
IMMAGE APB	24 months shelf-life 14 open container stability 14 day calibration stability

Estimated Within-Run Imprecision

Material	MEAN (mg/dL)	SD (mg/dL)	%CV	Number of Results
APA Reagent				
Level 1	56.7	3.12	5.5	80
Level 2	105	3.4	3.2	80
Level 3	167	4.8	2.9	80
APB Reagent				
Level 1	55.7	1.78	3.2	80
Level 2	115	2.9	2.5	80
Level 3	186	4.6	2.5	80

Beckman Instruments, Inc., Section 510(k) Notification
IMAGE™ Immunochemistry System Apolipoprotein A-1(APA) and B (APB) Reagents
Summary of Safety & Effectiveness

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.